Drug Utilization Review Board Meeting Minutes, Open Session January 10, 2018		
Drug Utilization Review Board Meeting Location: DXC Technology, Building #283, Capital Room 6511 SE Forbes Ave, Topeka, KS 66619	**DUR Board Members Present** Moneeshindra Mittal, MD, Chair LaTonyua Rice, Pharm.D., CGP John Kollhoff, Pharm.D., Interim Chair Tim Heston, DO Roger Unruh, DO James Backes, Pharm.D. (Phone) **DUR Board Members Absent** Judy Dowd, PA-C **DHCF Staff Present** Annette Grant, RPh Carol Arace, Sr. Administrative Assistant **DXC Technology Staff Present** Karen Kluczykowski, RPh Ellen McCaffrey, BSN, MSN Kathy Kaesewurm, RN, BSN **HID Staff Present** Taylor DeRuiter, Pharm.D. **MCO Staff Present** Angie Zhou, Pharm.D., Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh: Amerigroup	**Public Attendees:** Melissa Basil, Abbvie; Jim Baumann, Pfizer; Jeanie Brown, Novartis; Corinne Copeland, Alexion Brent Defrost; John Esslinger, UHC; Jeremy Franklin, Alexion; Katy Friedebach, SHP; Dr. Karl Haake (phone); Rob Hanson, Pfizer; Brent Hildebrand, Gilead; Laura Hill, Abbvie; Heather Jones, Novartis; Sarah Keek, Merck; Phil King, Pfizer; Josh Lang, NVS; Gay Thomas, BMS; Doug Wood

TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Mittal called the meeting to order at 10:00am. (Quorum not met)	
A. Announcements	Ms. Grant provided the standard parking announcement.	
II. Old Business **A. Review and Approval of October 11, 2017 Meeting Minutes**	**Board Discussion:** The October 11, 2017 meeting minutes were not available at this time. Quorum met at 10:10am.	Review and approval of the October 11, 2017 meeting minutes were tabled until the next DUR Board meeting in April 2018.
III. New Business **A. New Preferred Drug List (PDL) Class** 1. Short-Acting Opioids i. Non-Preferred PDL PA Criteria	**Background:** At the December 2017 PDL meeting, the committee approved the addition of the short-acting opioids to the PDL. Standard non-preferred prior authorization criteria are being proposed for this new class to allow access to non-preferred agents. **Public Comment:** None.	Dr. Heston moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Board Discussion: There was some discussion on why Codeine was not added. Determined to be an oversight and would be brought to the next PDL meeting for consideration.	
B. Revised Prior Authorization (PA) Criteria 1. Bydureon® (exentatide) i. Revised PA Criteria	**Background:** Bydureon is a glucagon-like peptide (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Prior authorization criteria were initially approved in April 2011.The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** None APPROVED PA Criteria Initial Approval: April 12, 2011 Revised Date: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Incretin mimetic agents **PROVIDER GROUP:** Pharmacy **MANUAL GUIDELINES:** The following drug(s) require prior authorization: Exenatide extended-release (Bydureon®), Exenatide auto-injector (Bydureon BCise®) **CRITERIA:** (must meet all of the following) • Patient must be at least 18 years old. • Patient must have a diagnosis of Type 2 Diabetes. o Diagnosis of Type 2 Diabetes must be documented by HbA1c > 6.5% • Patient must have HbA1c between 6.5% - 9.0% • Patient must have history of another antidiabetic agent in the previous 30 days. • Patient must not have history or family history of medullary thyroid carcinoma in the past 2 years. • Patient must not have history of multiple endocrine neoplasia syndrome type 2 in the past 2 years. **RENEWAL CRITERIA: (must meet one of the following)** • Documented improvement of HbA1c from pretreatment levels • Achievement or maintenance of therapeutic goals (HbA1c ≤ 6.5%) **Prior Authorization will be approved for 6 months.**	Dr. Unruh moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
B. Revised Prior Authorization (PA) Criteria 2. Cinryze® (C1 esterase inhibitor, human) i. Revised PA Criteria	**Background:** Cinryze is a protein C1 inhibitor indicated for the prophylaxis of hereditary angioedema (HAE) attacks. Prior authorization criteria for this agent was last revised in January 2016. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** None. APPROVED PA Criteria Initial Approval: July 8, 2009 Revised Date: January 10, 2018; January 13, 2016 **CRITERIA FOR PRIOR AUTHORIZATION** Cinryze® (C1 esterase inhibitor, human) **PROVIDER GROUP** Pharmacy Professional **MANUAL GUIDELINES** The following drug requires prior authorization: C1 esterase inhibitor, human (Cinryze®) **CRITERIA FOR PRIOR AUTHORIZATION FOR C1 ESTERASE INHIBITOR:** (must meet all of the following) • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for routine prophylaxis against angioedema attacks in patients with HAE • Patient must be 13 years of age or older **LENGTH OF APPROVAL: 12** months	Dr. Kollhoff moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 3. Ruconest® (C1 esterase inhibitor, recombinant) i. Revised PA Criteria	**Background:** Ruconest is a protein C1 inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria for this agent was last revised in January 2016. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** None.	Dr. Kollhoff moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: October 8, 2014 Revised Date: January 10, 2018; January 13, 2016 **CRITERIA FOR PRIOR AUTHORIZATION** Ruconest® (C1 esterase inhibitor, recombinant) **PROVIDER GROUP** Pharmacy Professional **MANUAL GUIDELINES** The following drug requires prior authorization: C1 esterase inhibitor, recombinant (Ruconest®) **CRITERIA FOR PRIOR AUTHORIZATION FOR C1 ESTERASE INHIBITOR:** (must meet all of the following) • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for the treatment of an acute attack of HAE • Must not be used for the treatment of a laryngeal HAE attack • Patient must be 13 years of age or older • Dose must not exceed 4200 units per dose, 2 doses per day **LENGTH OF APPROVAL:** 12 months	
B. Revised Prior Authorization (PA) Criteria 4. Firazyr® (icatibant) i. Revised PA Criteria	**Background:** Firazyr is a bradykinin inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria for this agent was last revised in January 2016. HAE is a genetic condition and is commonly diagnosed through a blood test measuring C1 inhibitor levels. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use. **Public Comment:** None. **Board Discussion:** None. APPROVED PA Criteria Initial Approval: July 11, 2012 Revised Date: January 10, 2018; January 13, 2016 **CRITERIA FOR PRIOR AUTHORIZATION** Firazyr® (icatibant) **PROVIDER GROUP** Pharmacy Professional **MANUAL GUIDELINES** The following drug requires prior authorization: Icatibant (Firazyr®) **CRITERIA FOR PRIOR AUTHORIZATION FOR ICATIBANT:** (must meet all of the following) • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for the treatment of an acute attack of HAE • Patient must be 18 years of age or older • Dose must not exceed 90 mg (3 doses) per 24 hours **LENGTH OF APPROVAL:** 12 months	Dr. Kollhoff moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
B. Revised Prior Authorization (PA) Criteria 5. Stelara® (ustekinumab) i. Revised PA Criteria	**Background:** Stelara is a biologic immunomodulator. Prior authorization criteria for this agent was last revised in January 2017. Since that time, the FDA has approved an expanded indication for Stelara for the treatment of patients 12 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. The prior authorization criteria are being revised to update approved indications and place in therapy. **Public Comment:** None. **Board Discussion:** None.	Dr. Kollhoff moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.

APPROVED PA Criteria

Initial Approval: January 13, 2010
Revised Dates: January 10, 2018; January 11, 2017; April 13, 2016; January 13, 2016; January 8, 2014; April 11, 2012; January 12, 2011

CRITERIA FOR PRIOR AUTHORIZATION

Stelara® (ustekinumab)

PROVIDER GROUP Pharmacy Professional

MANUAL GUIDELINES The following drug requires prior authorization: Ustekinumab (Stelara®)

CRITERIA FOR PLAQUE PSORIASIS (must meet all of the following):

- Patient must have a diagnosis of plaque psoriasis
- Must be prescribed by a rheumatologist or dermatologist
- Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval
- Patient must be 12 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days
- Patient must be a candidate for systemic therapy or phototherapy
- Dose must not exceed 45 mg per injection. If prescriber is seeking 90 mg per dose, documentation of the patient's weight is required and/or that 45 mg has not been efficacious

CRITERIA FOR PSORIATIC ARTHRITIS (PSA) (must meet all of the following):

- Patient must have a diagnosis of psoriatic arthritis
- Must be prescribed by a rheumatologist or dermatologist
- Evaluation for latent TB with TB skin test prior to initial prior authorization approval
- Patient must be 18 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days
- Dose must not exceed 45 mg per injection. If prescriber is seeking 90 mg per dose, documentation of patient's weight and coexisting moderate to severe plaque psoriasis is submitted

CRITERIA FOR CROHN'S DISEASE (CD) (must meet all of the following):

- Patient must have a diagnosis of Crohn's disease
- Patient must have one of the following:
  - failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker
  - failed or were intolerant to treatment with one or more TNF blockers
- Must be prescribed by a gastroenterologist
- Evaluation for latent TB with TB skin test prior to initial prior authorization approval
- Patient must be 18 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days

LENGTH OF APPROVAL 12 months

TOPIC	DISCUSSION	DECISION AND/OR ACTION
B. Revised Prior Authorization (PA) Criteria 6. Keytruda® (pembrolizumab) i. Revised PA Criteria	**Background:** Keytruda is a PD-L1 receptor targeted therapy for melanoma, non-small cell lung cancer and squamous cell carcinoma of the head and neck. Prior authorization criteria for this agent was last revised in January 2017. Since that time, Keytruda has been indicated for the treatment of a) recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma with disease progression on or after 2 or more prior lines of therapy; b) relapsed or refractory classical Hodgkin lymphoma; and c) unresectable or metastatic microsatellite instability-high or mismatch repair deficient cancers (solid tumors and colorectal cancer).The prior authorization criteria are being revised to update approved indications and place in therapy. **Public Comment:** None. **Board Discussion:** None.	Dr. Unruh moved to approve. Dr. Kollhoff seconded the motion. The motion was approved unanimously.

APPROVED PA Criteria

Initial Approval: October 12, 2016
Revised: January 10, 2018; January 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Keytruda® (pembrolizumab)

PROVIDER GROUP Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Pembrolizumab (Keytruda®)

CRITERIA FOR PRIOR AUTHORIZATION APPROVAL (must meet all of the following):

- Patient must have one of the following:
  - Diagnosis of unresectable or metastatic melanoma
    - Patients with BRAF V600 mutation positive tumor(s) should have disease progression (on approved V600 mutation directed therapy) prior to receiving pembrolizumab
  - Diagnosis of metastatic non-small cell lung cancer (NSCLC)
    - Have high PD-L1 expressing tumors (TPS ≥ 50%, as determined by a FDA approved test) without other genetic mutations and are treatment naive
    - Have PD-L1-expressing tumors (TPS ≥ 1% as determined by a FDA approved test) and have had disease progression on or after platinum-containing chemotherapy
    - Patients with EGFR or ALK genomic tumor aberrations should have disease progression (on approved EGFR- or ALK-directed therapy) prior to receiving pembrolizumab
  - Diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck
    - Have had disease progression on or after platinum-containing chemotherapy
  - Diagnosis of locally advanced or metastatic urothelial carcinoma
    - Patients with disease progression during or after platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy
    - Patients who are not eligible for cisplatin-containing treatment
  - Diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer
    - Have PD-L1-expressing tumors (CPS ≥ 1 as determined by a FDA approved test) and have had disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy, and if appropriate, HER2/neu-targeted therapy
  - Diagnosis of relapsed or refractory, classical Hodgkin Lymphoma
    - Patients with refractory classical Hodgkin lymphoma, or who have relapsed after 3 or more prior lines of therapy
  - Diagnosis of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors or colorectal cancer
    - Adult patients with MSI-H or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options
    - Pediatric patients with non-CNS MSI-H or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options
    - Patients with MSI-H or mismatch repair deficient colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan
- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Patient must meet one of the following age requirements based on diagnosis:
  - Patient must be 2 years of age or older for a diagnosis of classical Hodgkin Lymphoma or a diagnosis of MSI-H or mismatch repair deficient solid tumors or colorectal cancer

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TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria ○ Patient must be 18 years of age or older for all other diagnoses • Patient must not be pregnant or nursing • Must be administered by a healthcare professional • Dose does not exceed FDA approved maximum dosing limits ○ For melanoma, maximum dose is 2 milligrams per kilogram administered intravenously every 3 weeks ○ For all other diagnoses , maximum dose is 200 mg administered intravenously every 3 weeks for a maximum duration of 24 months **LENGTH OF APPROVAL:** 12 months Notes: • Information on FDA-approved tests for the detection of PD-L1 expression in NSCLC is available at: http://www.fda.gov/CompanionDiagnostics.	
B. Revised Prior Authorization (PA) Criteria 7. Daraprim® (pyrimethamine) i. Revised PA Criteria	**Background:** Daraprim had a typographical error during the initial approval in July 2017. **Public Comment:** None. **Board Discussion:** None. APPROVED PA Criteria Initial Approval: July 26, 2017 Revised Dates: January 10, 2018; October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Daraprim® (pyrimethamine) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: The following drug requires prior authorization: Pyrimethamine (Daraprim®) CRITERIA FOR INITIAL APPROVAL (must meet all of the following): • Patient must have one of the following: ○ Treatment of acute toxoplasmosis ▪ Patient must be taking in combination with a sulfonamide/sulfadiazine and folinic acid ○ Primary prophylaxis of toxoplasmosis with HIV ▪ Patient must be taking in combination with 1) dapsone/leucovorin or 2) atovaquone/leucovorin ▪ Patient must be currently taking ART (anti-retroviral therapy) ▪ Patient must have a previous trial of or contraindication to Bactrim (sulfamethoxazole/trimethoprim; TMP-SMZ) ○ Treatment of chronic maintenance (secondary prophylaxis) therapy of toxoplasmosis with HIV ▪ Patient must be taking in combination with a 1) sulfadiazine/leucovorin or 2) clindamycin/leucovorin or 3) atovaquone/leucovorin ▪ Patient must be currently taking ART (anti-retroviral therapy) ○ Treatment of T. gondii encephalitis ▪ Patient must be taking in combination with 1) a sulfadiazine/leucovorin or 2) leucovorin plus clindamycin or atovaquone or azithromycin • Patient must not have a documented megaloblastic anemia due to folate deficiency LENGTH OF APPROVAL: Acute toxoplasmosis: 8 weeks Maintenance toxoplasmosis: 6 months Primary prophylaxis against toxoplasmosis: 6 months T. gondii encephalitis: 6 weeks CRITERIA FOR RENEWAL (must meet all of the following): • Patient must have one of the following: ○ Primary prophylaxis of toxoplasmosis with HIV ▪ Patient must be taking in combination with dapsone/leucovorin or atovaquone/leucovorin ▪ Patient must be currently taking ART (anti-retroviral therapy) ▪ Patient must have a CD4 count less than 200 cells/mm² or CD4 is greater than 200 for a period of less than 3 consecutive months (documentation required) ○ Treatment of chronic maintenance (secondary prophylaxis) therapy of toxoplasmosis with HIV ▪ Patient must be taking in combination with a sulfadiazine/leucovorin or clindamycin/leucovorin or atovaquone/leucovorin ▪ Patient must be currently taking ART (anti-retroviral therapy) ▪ Patient must have a CD4 count less than 200 cells/mm² or CD4 is greater than 200 for a period of less than 6 consecutive months (documentation required) • Patient must not have a documented megaloblastic anemia due to folate deficiency LENGTH OF APPROVAL: Maintenance toxoplasmosis: 6 months Page 1 of 2	Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Primary prophylaxis against toxoplasmosis: 6 months Notes: • Sulfonamide: sulfadoxine, sulfadiazine • Current Centers for Disease Control and Prevention recommendations for malaria prophylaxis and treatment do not include the use of pyrimethamine; resistance to pyrimethamine is prevalent worldwide.	
B. Revised Prior Authorization (PA) Criteria 8. Opdivo® (nivolumab) i. Revised PA Criteria	**Background:** Opdivo is an antineoplastic monoclonal antibody. Prior authorization criteria were last revised in October 2017. Since that time, Opdivo has become indicated for the treatment of hepatocellular carcinoma who have been previously treated with sorafenib. The prior authorization criteria are being revised to update approved indications and place in therapy. **Public Comment:** Gay Thomas with BMS spoke on behalf of Opdivo®. Asking the Board to consider adding a new indication approved by the FDA of Adjuvent treatment of melanoma with lymph node involvement or metastatic disease who have undergone complete resection. **Board Discussion:** The Board granted Ms. Thomas' request and the indication was added to the criteria. APPROVED PA Criteria Initial Approval: October 14, 2015 Revised Dates: January 10, 2018; October 11, 2017; April 12, 2017; October 12, 2016; April 13, 2016 CRITERIA FOR PRIOR AUTHORIZATION Opdivo® (nivolumab) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: The following drug requires prior authorization: Nivolumab (Opdivo®) CRITERIA FOR APPROVAL (must meet all of the following): • Patient must have one of the following diagnoses: ○ Unresectable or metastatic melanoma ▪ Medication must be used as a single agent or in combination with ipilimumab ○ Adjuvant treatment of melanoma with lymph node involvement or metastatic disease who have undergone complete resection ○ Metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy ▪ If EGFR or ALK mutation present, patient must have failure with a mutation specific medication prior to using Opdivo ○ Advanced renal cell carcinoma ▪ Patient must have received prior anti-angiogenic therapy ○ Classical Hodgkin lymphoma that has relapsed or progressed after one of the following: ▪ Autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin ▪ Three or more lines of systemic therapy that included autologous HSCT ○ Recurrent or metastatic squamous cell carcinoma of the head and neck (HNSCC) with disease progression on or after platinum-based chemotherapy ○ Locally advanced or metastatic urothelial carcinoma who: ▪ Have disease progression during or following platinum-containing chemotherapy ▪ Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy ○ Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer ▪ Must be 12 years of age or older ▪ Has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan ○ Hepatocellular carcinoma in patients who have been previously treated with sorafenib • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older, unless being used for MSI-H or dMMR metastatic colorectal cancer • LENGTH OF APPROVAL: 12 months	Dr. Kollhoff moved to approve the criteria as amended. Dr. Rice seconded the motion. The motion was approved unanimously.

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<td>B. Revised Prior Authorization (PA) Criteria
9. Pegasys® (peginterferon alfa-2a)
i. Revised PA Criteria</td>
<td><u>Background:</u>
Pegasys is an alpha interferon, indicated for the treatment of hepatitis B and hepatitis C. Prior authorization criteria were initially approved in July 2013. Since that time, Pegasys has become indicated for the treatment of hepatitis B in noncirrhotic pediatric patients 3 years and older with HBeAg-positive chronic hepatitis B. The prior authorization criteria are being revised to update approved indications and place in therapy.
<u>Public Comment:</u>
None.
<u>Board Discussion:</u>
None.
APPROVED PA Criteria
Initial Approval: July 10, 2013
Revised Dates: January 10, 2018
CRITERIA FOR PRIOR AUTHORIZATION
Alpha Interferon
PROVIDER GROUP Pharmacy Professional
MANUAL GUIDELINES The following drug requires prior authorization: Peginterferon alfa-2a (Pegasys®)
CRITERIA FOR CHRONIC HEPATITIS B Must meet all of the following:
• Patient must have a diagnosis of chronic hepatitis B (HBV)
• Patient must have been serum HBsAg positive for at least 6 months
• Patient must have evidence of HBV replication defined as one of the following
○ HBeAg positive patients – HBV DNA level >20,000 IU/mL
○ HBeAg negative patients – HBV DNA level ≥2,000 IU/mL
• Patient must have evidence of active liver disease demonstrated by one of the following
○ persistent elevation in serum ALT (≥2 times upper limits of normal)
○ moderate to severe hepatitis or fibrosis on biopsy
○ evidence of icteric ALT flare ups
• Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
• Patient must not have decompensated liver disease
• Must meet one of the following age criteria:
○ Patients with HBeAg-positive chronic HBV infection must be 3 years of age or older
○ Patients with HBeAg-negative chronic HBV infection must be 18 years of age or older
• Patient has not previously completed a full course of therapy with interferon or peginterferon
LENGTH OF APPROVAL FOR CHRONIC HEPATITIS B 48 weeks</td>
<td>Dr. Unruh moved to approve.

Dr. Heston seconded the motion.

The motion was approved unanimously.</td>
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<td>B. Revised Prior Authorization (PA)</td>
<td><u>Background:</u>
The SGLT2 inhibitor combinations prior authorization criteria was last revised in October</td>
<td>Dr. Unruh moved to approve.</td>
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<td>Criteria
10. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor Combinations
i. Revised PA Criteria</td>
<td>2017. This revision had a typographical error during approval which has since been corrected.
<u>Public Comment:</u>
None.
<u>Board Discussion:</u>
None.
APPROVED PA Criteria
Initial Approval: April 8, 2015
Revised Date: January 10, 2018; October 11, 2017;
April 12, 2017; October 12, 2016;
July 13, 2016
CRITERIA FOR PRIOR AUTHORIZATION
Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor Combinations
PROVIDER GROUP Pharmacy
MANUAL GUIDELINES The following drug requires prior authorization:
Canagliflozin/metformin (Invokamet®, Invokamet XR®)
Dapagliflozin/metformin (Xigduo XR®)
Dapagliflozin/saxagliptin (Qtern®)
Empagliflozin/linagliptin (Glyxambi®)
Empagliflozin/metformin (Synjardy®, Synjardy XR®)
CRITERIA FOR PRIOR AUTHORIZATION FOR SGLT2 INHIBITOR COMBINATIONS: (must meet all of the following)
• Patient must have a diagnosis of type II diabetes
• Patient MUST NOT have a diagnosis of type I diabetes
• Patient must be 18 years of age or older
• Patient must have an eGFR above:
○ 45 mL/min/1.73m^2 (Glyxambi, Invokamet, Synjardy, Qtern)
○ 60 mL/min/1.73m^2 (Xigduo XR)
• Patient MUST NOT have any of the following contraindications:
○ End-stage renal disease
○ Currently on dialysis
• Patient must have a trial of a preferred metformin ER agent at a maximum tolerated dose
LENGTH OF APPROVAL: 12 months</td>
<td>Dr. Kollhoff seconded the motion.

The motion was approved unanimously.</td>
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<td>B. Revised Prior Authorization (PA) Criteria
11. Simponi®, Simponi Aria® (golimumab)
i. Revised PA Criteria</td>
<td><u>Background:</u>
Simponi is an immunomodulator. Prior authorization criteria were initially approved in April 2016. Since that time, Simponi Aria has become indicated for the treatment of a) psoriatic arthritis and b) active ankylosing spondylitis. The prior authorization criteria are being revised to update approved indications and place in therapy.
<u>Public Comment:</u>
None.
<u>Board Discussion:</u>
None.</td>
<td>Dr. Unruh moved to approve.

Dr. Rice seconded the motion.

The motion was approved unanimously.</td>
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TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: July 8, 2009 Revised Dates: January 10, 2018; April 13, 2016; July 10, 2013; April 11, 2012 **CRITERIA FOR PRIOR AUTHORIZATION** Simponi ® (golimumab) Simponi Aria® (golimumab) **PROVIDER GROUP** Pharmacy Professional **MANUAL GUIDELINES** The following drug requires prior authorization: Golimumab (Simponi®, Simponi Aria®) **CRITERIA FOR RHEUMATOID ARTHRITIS (RA)** Must meet all of the following: • Patient must have a diagnosis of moderate to severe, active rheumatoid arthritis • Must be given in combination with methotrexate, unless patient has a contraindication to methotrexate • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent tuberculosis (TB) with a TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **CRITERIA FOR PSORIATIC ARTHRITIS (PSA)** Must meet all of the following: • Patient must have a diagnosis of active psoriatic arthritis • Must be prescribed by or in consultation with a rheumatologist or dermatologist • Patient must have an evaluation for latent TB with a TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **CRITERIA FOR ANKYLOSING SPONDYLITIS (AS)** Must meet all of the following: • Patient must have a diagnosis of active Ankylosing spondylitis • Must be prescribed by or in consultation with a rheumatologist • Patient must have an evaluation for latent TB with a TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days	

TOPIC	DISCUSSION	DECISION AND/OR ACTION

	APPROVED PA Criteria
	CRITERIA FOR ULCERATIVE COLITIS (UC) Must meet all of the following:
	• Request must be for Simponi (not Simponi Aria)
	• Patient must have a diagnosis of moderate to severe, active ulcerative colitis
	• Patient must meet one of the following
	  ○ Patient has had an inadequate response to or failed to tolerate one of the following
	  ▪ oral aminosalicylates
	  ▪ oral corticosteroids
	  ▪ azathioprine
	  ▪ 6-mercaptopurine
	  ○ Patient has an inability to taper corticosteroids without a return of the symptoms of UC (i.e., patient is corticosteroid dependent)
	• Patient must have an evaluation for latent TB with a TB skin test prior to initial prior authorization approval
	• Patient must be 18 years of age or older
	• Patient has not taken another biologic agent (see attached table) in the past 30 days
	LENGTH OF APPROVAL 12 months	

B. Revised Prior Authorization (PA) Criteria 12. Soliris® (eculizumab) i. Revised PA Criteria	**Background:** Soliris is a complement inhibitor, indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria to reduce hemolysis, and the treatment of patients with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy. Prior authorization criteria were initially approved in October 2013. Since that time, Soliris has become indicated for the treatment of generalized myasthenia gravis who are anti-acetylcholine receptor antibody-positive. The prior authorization criteria are being revised to update approved indications and place in therapy. **Public Comment:** Dr. Jeremy Franklin with Alexion yielded his time back to the Board with the offer to answer any questions they may have concerning Soliris. **Board Discussion:** None.	Dr. Kollhoff moved to approve. Dr. Heston seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

	APPROVED PA Criteria
	
	Initial Approval: October 9, 2013
	Revised Dates: January 10, 2018
	
	CRITERIA FOR PRIOR AUTHORIZATION
	
	Soliris® (eculizumab)
	
	PROVIDER GROUP Pharmacy Professional
	
	MANUAL GUIDELINES The following drug requires prior authorization: Eculizumab (Soliris®)
	
	CRITERIA FOR PAROXYSMAL NOCTURNAL HEMOGLOBINURIA Must meet all of the following:
	
	• Patient must have a diagnosis of paroxysmal nocturnal hemoglobinuria
	• Patient must be 18 years of age or older
	• Patient must not have an unresolved serious *Neisseria meningitidis* infection
	• Patient must be vaccinated against *Neisseria meningitidis* at least 2 weeks prior to initiation of therapy with Soliris unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection
	
	CRITERIA FOR ATYPICAL HEMOLYTIC UREMIC SYNDROME Must meet all of the following:
	
	• Patient must have a diagnosis of atypical hemolytic uremic syndrome (aHUS)
	• The diagnosis of aHUS is supported by the absence of Shiga toxin-producing *E. coli* infection
	• Patient must be 2 months of age or older
	• Patient must not have an unresolved serious *Neisseria meningitidis* infection
	• Patient must be vaccinated against *Neisseria meningitidis* at least 2 weeks prior to initiation of therapy with Soliris unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection
	
	CRITERIA FOR GENERALIZED MYASTHENIA GRAVIS Must meet all of the following:
	
	• Patient must have a diagnosis of generalized myasthenia gravis (gMG)
	• Patient must be Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
	• Patient must have a MG-Activities of Daily Living (MG-ADL) total score ≥6
	• Patient must meet one of the following:
	  ○ Patient has previously experienced treatment failure with two or more immunosuppressive therapies
	  ○ Patient has previously experienced treatment failure with at least one immunosuppressive therapies AND required one of the following
	  ▪ Chronic plasmapheresis
	  ▪ Plasma exchange (PE)
	  ▪ Intravenous immunoglobulin.
	• Patient must be 18 years of age or older
	• Patient must not have an unresolved serious *Neisseria meningitidis* infection	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria • Patient must be vaccinated against *Neisseria meningitidis* at least 2 weeks prior to initiation of therapy with Soliris unless the risks of delaying Soliris treatment outweigh the risks of developing a meningococcal infection **LENGTH OF APPROVAL** 3 months	
B. Revised Prior Authorization (PA) Criteria 13. Zelboraf® (vemurafenib) i. Revised PA Criteria	**Background:** Zelboraf is a kinase inhibitor, indicated for the treatment of patients with unresectable and/or metastatic melanoma with a BRAF V600E mutation. Prior authorization criteria were initially approved in October 2015. Since that time, Zelboraf has become indicated for the treatment of Erdheim-Chester disease with BRAF V600 mutation. The prior authorization criteria are being revised to update approved indications and place in therapy. **Public Comment:** None. **Board Discussion:** None. APPROVED PA Criteria Initial Approval: October 14, 2015 Revised Dates: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Zelboraf® (vemurafenib) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: vemurafenib (Zelboraf®) **CRITERIA FOR ZELBORAF (VEMURAFENIB):** (MUST MEET ALL OF THE FOLLOWING) • Patient must have a diagnosis of one of the following: ○ Unresectable or metastatic melanoma with a BRAF V600E mutation, confirmed by a FDA-approved test ○ Erdheim-Chester disease with a BRAF V600E mutation, confirmed by a FDA-approved test • Must be prescribed by or in consultation with an oncologist **LENGTH OF APPROVAL:** 12 months	Dr. Kollhoff moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
B. Revised Prior Authorization (PA) Criteria 14. Zinplava® (bezlotoxumab) i. Revised PA	**Background:** Zinplava is a human monoclonal antibody that binds to Clostridium difficile toxin B and is indicated to reduce recurrence of infections in adults who are receiving antibiotic treatment for Clostridium difficile infection (CDI). Prior authorization criteria were initially approved in January 2017. The criteria is being updated to address the use of Zinplava in patients with a	Dr. Kollhoff moved to approve. Dr. Heston seconded the motion. The motion was approved

TOPIC	DISCUSSION	DECISION AND/OR ACTION
Criteria	diagnosis of HIV/AIDS or those that are receiving chemotherapy. **Public Comment:** None. **Board Discussion:** Ms. Grant responded to the question of why the update was needed. Ms. Grant said the State received a request to consider less previous episodes required for sub-populations with compromised immune systems. Through internal discussion the request seem reasonable and was brought before the DUR board today for consideration.	unanimously.

APPROVED PA Criteria

Initial Date: January 11, 2017
Revised Date: January 10, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Zinplava® (bezlotoxumab)

PROVIDER GROUP: Pharmacy

MANUAL GUIDELINES: The following drug(s) requires prior authorization:
Bezlotoxumab (Zinplava®)

CRITERIA FOR PRIOR AUTHORIZATION (must meet all of the following):

- Patient must have diagnosis of *Clostridium difficile* infection (CDI) confirmed by documentation of positive toxin B *Clostridium difficile* test, or that the facility is unable to test for toxins (would only require a positive CDI)
- Patient will receive or is currently receiving concomitant antibacterial drug treatment for CDI (e.g. metronidazole, vancomycin, fidaxomicin)
- Must meet one of the following:
  - Patient has had at least two episodes of CDI recurrence (3 episodes) in the previous 6 months and has been treated with appropriate treatment for CDI*, including a pulsed vancomycin regimen
  - Patient has had at least one previous episode of CDI in the previous 6 months treated with appropriate treatment for CDI*, including a pulsed vancomycin regimen, and has a diagnosis of HIV/AIDs or is receiving chemotherapy
- Dosing frequency must not exceed 1 dose

APPROVAL LENGTH: 1 dose

Notes:

- Recurrent episodes of CDI are treated with metronidazole, vancomycin, or fidaxomicin. The first recurrence should be treated with the same treatment as the initial episode. The second recurrence should be treated with vancomycin in a pulsed regimen and the third recurrence with a pulsed regimen and consideration for fecal microbiata transplant.
  - Metronidazole: 500 mg orally 3 times per day for 10 - 14 days
  - Vancomycin: 125 mg orally 4 times per day for 10 days
  - Fidaxomicin: 200 mg orally twice daily for 10 days
  - Pulsed Vancomycin: 10 days course of vancomycin at 125 mg four times per day, followed 125 mg daily pulsed every 3 days for 10 doses
- Repeat dosing is not recommended

<table>
<tr><th>TOPIC</th><th>DISCUSSION</th><th>DECISION AND/OR ACTION</th></tr>
<tr>
<td>B. Revised Prior Authorization (PA) Criteria
15. Makena® (hydroxyprogesterone caproate)
i. Revised PA Criteria</td>
<td><u>Background:</u>
Makena is a progestin indicated for the prevention of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Prior authorization criteria were last revised in July 2016. The criteria is being updated to allow for treatment with Makena to be used for up to 26 weeks, 6 days of gestation.
<u>Public Comment:</u>
None.
<u>Board Discussion:</u>
None.
APPROVED PA Criteria
Effective Date: June 15, 2011
Revised Dates: January 10, 2018; July 13, 2016
CRITERIA FOR PRIOR AUTHORIZATION
Makena® (hydroxyprogesterone caproate)
PROVIDER GROUP Pharmacy
Professional
MANUAL GUIDELINES The following drug requires prior authorization:
Hydroxyprogesterone Caproate (Makena®)
CRITERIA FOR INITIAL PRIOR AUTHORIZATION FOR HYDROXYPROGESTERONE CAPROATE: (must meet all of the following)
• Patient must have a singleton pregnancy
• Patient must have a history of singleton spontaneous preterm birth.
• Patient must be 16 years of age or older.
• Treatment must begin between 16 weeks, 0 days and 26 weeks, 6 days of gestation.
• Treatment must stop at week 37 (through 36 weeks, 6 days) gestation or delivery, whichever occurs first.
LENGTH OF APPROVAL: Up to 20 weeks
Limit one (1) mL every (1) week with a total quantity limit of twenty (20) mL per pregnancy</td>
<td>Dr. Kollhoff moved to approve.

Dr. Heston seconded the motion.

The motion was approved unanimously.</td>
</tr>
<tr>
<td>C. New Prior Authorization (PA) Criteria
1. Cabometyx® (cabozantinib)
i. Prior Authorization Criteria</td>
<td><u>Background:</u>
Cabometyx is a pro-invasive receptor tyrosine kinase inhibitor, indicated for the treatment of advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
<u>Public Comment:</u>
None.
<u>Board Discussion:</u>
None.</td>
<td>Dr. Heston moved to approve.

[Inaudible] seconded the motion.

The motion was approved unanimously.</td>
</tr>
</table>

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Cabometyx® (cabozantinib) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: cabozantinib (Cabometyx®) **CRITERIA FOR APPROVAL** (must meet all of the following): • Patient must have a diagnosis advanced renal cell carcinoma (RCC) • Patient must have a Karnofsky Performance Score (KPS) ≥ 70% • Patient must meet one of the following: o Females: not be pregnant (verified negative pregnancy test prior to initiating treatment for those of reproductive potential) or breastfeeding and be advised to not become pregnant or breastfeed for at least 4 months after the final dose o Males: advised to use effective contraception (e.g. condoms) during treatment and for at least 4 months after the final dose • Patient must be 18 years of age or older • Dose must not exceed 80 mg daily **CRITERIA FOR RENEWAL** (must meet all of the following): • Patient must not have experienced any of the following while on Cabometyx: o Recent history of severe hemorrhage o GI fistulas that cannot be adequately managed or perforations o Arterial thromboembolic event (e.g., myocardial infarction, cerebral infarction) o Nephrotic syndrome o Reversible posterior leukoencephalopathy syndrome o Hypertensive crisis or severe hypertension that cannot be controlled with antihypertensive medications • Dose must not exceed 80 mg daily **LENGTH OF APPROVAL:** 12 months	
C. New Prior Authorization (PA) Criteria 2. Calquence® (acalabrutinib) i. Prior Authorization Criteria	**Background:** Calquence is a second-generation Bruton's tyrosine kinase (BTK) inhibitor, indicated for the treatment of mantle cell lymphoma (MCL) in patients who have received at least 1 prior therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information. **Public Comment:** None. **Board Discussion:** Dr. Kollhoff asked the MCOs what they do for new indications that become available before being brought to the DUR Board for approval. Dr. Zhou noted during the initial review, new indications may be missed, however, during the secondary review, the PA would be approved with what is found to be a FDA approved indication	Dr. Kollhoff moved to approve. Dr. Rice seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Calquence® (acalabrutinib) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: acalabrutinib (Calquence®) **CRITERIA FOR APPROVAL** (must meet all of the following): • Patient must have a diagnosis of mantle cell lymphoma (MCL) • Patient must have received at least 1 FDA-approved prior therapy for the treatment of MCL • Patient must not be pregnant • Patient must be at least 18 years of age • Dose must not exceed 100 mg twice daily **LENGTH OF APPROVAL:** 12 months	
C. New Prior Authorization (PA) Criteria 3. Elaprase® (idursulfase) Prior Authorization Criteria	**Background:** Elaprase is a recombinant form of iduronate-2-sulfatase, indicated for patients with Hunter syndrome (mucopolysaccharidosis type II [MPS II]) to improve walking capacity in patients 5 years and older. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information. **Public Comment:** None. **Board Discussion:** None. APPROVED PA Criteria Initial Approval: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Elaprase® (idursulfase) **PROVIDER GROUP** Professional **MANUAL GUIDELINES** The following drug requires prior authorization: idursulfase (Elaprase®) **CRITERIA FOR APPROVAL** (must meet all of the following): • Patient must have a diagnosis of Hunter syndrome (mucopolysaccharidosis type II) • The patient's baseline 6-minute walk test results must be provided • Patient must be 5 years of age or older • Dose must not exceed 0.5 mg/kg given as an IV infusion once a week **CRITERIA FOR RENEWAL** (must meet all of the following): • The patient's current 6-minute walk test results must be provided and show an increase in the distance walked • Dose must not exceed 0.5 mg/kg given as an IV infusion once a week **LENGTH OF APPROVAL:** 12 months	Dr. Heston moved to approve. Dr. Unruh seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. New Prior Authorization (PA) Criteria 4. Kymriah® (tisagenlecleucel) i. Prior Authorization Criteria	**Background:** Kymriah is a T cell immunotherapy, indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information. **Public Comment:** Jeanie Brown with Novartis spoke on behalf of Kymriah. **Board Discussion:** Jeanie Brown provided clarification of cost, dosing, and administering of the agent. The Board made changes to length of approval, removal of a sub-bullet that did not meet the agent's process, and creating the fourth bullet.	Dr. Unruh moved to approve as amended. Dr. Kollhoff seconded the motion. The criteria were approved unanimously.

APPROVED PA Criteria

Initial Approval: January 10, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Kymriah® (tisagenlecleucel)

PROVIDER GROUP Professional

MANUAL GUIDELINES The following drug requires prior authorization:
tisagenlecleucel (Kymriah®)

CRITERIA FOR APPROVAL (must meet all of the following):

- Patient must have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
- Documentation of CD19 tumor expression
- The patient must have acute lymphoblastic leukemia that is refractory or in second or later relapse defined as the following:
  - Second or greater bone marrow relapse,

  OR
  - Not achieving a complete response after 2 cycles of standard chemotherapy
- If disease is Philadelphia chromosome positive (must meet the following):
  - The patient must have experienced treatment failure with 2 tyrosine kinase inhibitors (TKI) (e.g. imatinib, dasatinib, nilotinib, bosutinib, ponatinib) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; (Prior authorization is required for selected TKI)
- Patient must be less than or equal to 25 years of age
- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Patient must not have any active infection or active inflammatory process
- Patient must meet the following (if applicable):
  - Females: not be pregnant (verified negative pregnancy test prior to initiating treatment for those of reproductive potential) and be advised to not become pregnant during treatment
- The patient must be receiving the medication from a healthcare facility that is enrolled and in compliance with the Kymriah REMS requirements
- Patient has not received prior CAR-T therapy
- Dose must not exceed the recommended dose based on weight (below)
  - For patients 50 kg or less: administer 0.2 to 5.0 x 10^6 chimeric antigen receptor (CAR)-positive viable T cells per kg body weight
  - For patients weighing greater than 50 kg: administer 0.1 to 2.5 x 10^8 CAR-positive viable T cells per kg body weight

LENGTH OF APPROVAL: 1 YEAR

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. New Prior Authorization (PA) Criteria 5. Lyrica® and Lyrica®CR (pregabalin and pregabalin CR) i. Prior Authorization Criteria	**Background:** Lyrica is an anti-epileptic medication, indicated for the treatment of fibromyalgia, postherpatic neuralgia, partial-onset seizures, and neuropathic pain associated with diabetic peripheral neuropathy and spinal cord injury. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and includes step therapy to ensure cost-effective use. **Public Comment:** Representatives with Pfizer spoke on behalf of Lyrica. **Board Discussion:** Dr. Kollhoff made the request to the Pfizer representatives to send the DUR Board a list of off label uses that have good level of evidence for the usage of Lyrica. The Board requested head-to-head data on Lyrica, Duloxetine, and Gabapentin. The Board denied the step therapy edits due to concern for limiting this agent, while at the same time we are looking for non-opioid pain remedies. Ms. Grant stated that while the State might consider off-label use for Lyrica, the State is not committed at this point to add off-label uses for this expensive drug, unless other less expensive off-label treatments could also be considered.	Dr. Rice and Dr. Kollhoff moved to have the step edits removed with the stipulation to bring this agent back to the next [April 2018] meeting with data and off label information. Dr. Backus seconded the motion. The motion was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Lyrica® (pregabalin), Lyrica CR® (pregabalin) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: pregabalin (Lyrica®, Lyrica CR®) **CRITERIA FOR APPROVAL FOR DIAGNOSIS OF PARTIAL-ONSET SEIZURE** (must meet all of the following): • Patient must have a diagnosis of partial-onset seizure • Request must be for immediate release Lyrica • Patient must be 18 years of age or older • Dose must not exceed 600 mg per day **CRITERIA FOR APPROVAL FOR DIAGNOSIS OF NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY** (must meet all of the following): • Patient must have a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy • Patient must be 18 years of age or older • Dose must not exceed the maximum recommended dose for the patient's diagnosis ○ Immediate Release: Dose must not exceed 300 mg per day ○ Extended Release: Dose must not exceed 330 mg per day **CRITERIA FOR APPROVAL FOR DIAGNOSIS OF POSTHERPETIC NEURALGIA** (must meet all of the following): • Patient must have a diagnosis of postherpetic neuralgia • Patient must be 18 years of age or older • Dose must not exceed the maximum recommended dose for the patient's diagnosis ○ Immediate Release: Dose must not exceed 600 mg per day ○ Extended Release: Dose must not exceed 660 mg per day **CRITERIA FOR APPROVAL FOR DIAGNOSIS OF FIBROMYALGIA** (must meet all of the following): • Patient must have a diagnosis of fibromyalgia • Request must be for immediate release Lyrica • Patient must be 18 years of age or older • Dose must not exceed 450 mg per day **CRITERIA FOR APPROVAL FOR DIAGNOSIS OF NEUROPATHIC PAIN ASSOCIATED WITH SPINAL CORD INJURY** (must meet all of the following): • Patient must have a diagnosis of neuropathic pain associated with spinal cord injury • Request must be for immediate release Lyrica • Patient must be 18 years of age or older • Dose must not exceed 600 mg per day **LENGTH OF APPROVAL:** 12 months	
C. New Prior Authorization (PA) Criteria 6. Trelegy Ellipta® (fluticasone/umeclidinium/vilanterol) i. Prior Authorization Criteria	**Background:** Trelegy Ellipta is a combination product consisting of an inhaled corticosteroid, anticholinergic, and long-acting beta agonist. It is indicated for chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication. **Public Comment:** None. **Board Discussion:** None.	Dr. Kollhoff moved to approve. Dr. Heston seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Trelegy Ellipta® (Fluticasone/Umeclidinium/Vilanterol) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: Trelegy Ellipta® (Fluticasone/Umeclidinium/Vilanterol) **CRITERIA FOR APPROVAL** (must meet all of the following): • Patient must have a diagnosis of chronic obstructive pulmonary disease (COPD) • Must meet one of the following: ○ Patient is currently on a fixed-dose combination of fluticasone and vilanterol for airflow obstruction and reducing exacerbations and require additional therapy ○ Patient is currently receiving umeclidinium and a fixed-dose combination of fluticasone and vilanterol • Patient must be 18 years of age or older • Dose must not exceed one inhalation per day **LENGTH OF APPROVAL:** 12 months	
C. New Prior Authorization (PA) Criteria 7. Trelstar® (triptorelin) i. Prior Authorization Criteria	**Background:** Trelstar is a gonadotropin releasing hormone (GnRH) agonist, indicated for the palliative treatment of advanced prostate cancer treatment. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information. **Public Comment:** None. **Board Discussion:** None.	Dr. Kollhoff moved to approve Dr. Heston seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Trelstar® (triptorelin) **PROVIDER GROUP** Professional **MANUAL GUIDELINES** The following drug requires prior authorization: triptorelin (Trelstar®) **CRITERIA FOR APPROVAL** (must meet all of the following): • Patient must have a diagnosis of advanced prostate cancer • Medication must be used for palliative treatment of advanced prostate cancer • Patient must not have a known hypersensitivity to triptorelin, other GnRH agonists or GnRH • Medication must be administered under the supervision of a health care provider • Patient must be 18 years of age or older • Dose is not to exceed 3.75 mg once every 4 weeks, or 11.25 mg once every 12 weeks, or 22.5 mg once every 24 weeks **LENGTH OF APPROVAL:** 12 months	
C. New Prior Authorization (PA) Criteria 8. Verzenio™ (abemaciclib) i. Prior Authorization Criteria	**Background:** Verzenio is a cyclin-dependent kinase (CDK) inhibitor, indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression following endocrine therapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication. **Public Comment:** None. **Board Discussion:** None.	Dr. Kollhoff moved to approve. Dr. Heston seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA Criteria Initial Approval: January 10, 2018 **CRITERIA FOR PRIOR AUTHORIZATION** Verzenio™ (abemaciclib) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: abemaciclib (Verzenio™) **CRITERIA FOR APPROVAL** (must meet all of the following): • Patient must have a diagnosis of advanced or metastatic breast cancer • The tumor must be hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative • Patient must have experienced disease progression following endocrine-based therapy • Must meet one of the following: o Patient is postmenopausal and will be using the medication in combination with fulvestrant o Patient is pre- or perimenopausal and will be using the medication in combination with fulvestrant and a gonadotropin releasing hormone agonist o Medication is being used as monotherapy and patient has experienced disease progression following prior chemotherapy in the metastatic setting of breast cancer • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older • Patient must not be pregnant or breastfeeding and be advised to not become pregnant for at least 3 weeks after the last dose • Dose does not exceed FDA approved maximum dosing limits: o Monotherapy: 200 mg twice daily o Combination therapy: 150 mg twice daily **LENGTH OF APPROVAL:** 12 months Notes: • When co-administered with fulvestrant, recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29; and once monthly thereafter. • Gonadotropin releasing hormone agonists used in breast cancer: Lupron (leuprolide) and Zoladex (goserelin).	
Dr. Mittal Recessed the meeting at 12:02pm. Dr. Mittal called the meeting back to order at 12:14pm.		
C. New Prior Authorization (PA) Criteria 9. Opioids i. Prior Authorization	**Background:** This criteria will combine and supersede all previous criteria for past opioid PAs, for both short and long acting opioids. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with	Section 1: Dr. Kollhoff moved to approve as amended.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
Criteria	similar agents. CDC guidelines, CMS Best Practices, and input from an internal team composed of members from DXC, KDHE, KDADS, and the MCOs was used for guidance in this draft. **Public Comment:** **Board Discussion:** The Chair recommended discussion and voting be done per section of this criteria. ***Section 1:*** **Public Comment:** None. **Board Discussion:** Recommend removing the 4th bullet 'Prescriber must be enrolled in the Opana® ER REMS program to prescribe for Opana ER®' as it is CMS recommended not required. Removed the 'Methadone is only approved for diagnosis of terminal cancer pain.' bullet as it is used primarily in a controlled environment care. ***Section 2:*** **Public Comment:** None. **Board Discussion:** Recommended changing 'failed' in the first sub-bullet under the second bullet to 'attempted treatment with'. Removing the 4th bullet 'Prescriber must be enrolled in the Opana® ER REMS program to prescribe for Opana ER®' as it is CMS recommended not required. Removing Dose Optimization/Other Limits from the Short Acting tables. ***Section 3:*** **Public Comment:** None. **Board Discussion:** Removed sub-bullet 'Prescriber must be enrolled in the Opana® ER REMS program to prescribe for Opana ER®' from the first bullet information. Removed the 'Fentanyl patches are only approved for patients with a diagnosis of cancer or for palliative care related pain.' from the now number 8 sub-bullet information. Added '(excluding patients in a long-term care facility)' to the 5th and 7th sub-bullets and changed the wording in the 8th sub-bullet to 'one of the following criteria must be met:' under Renewal Authorization Criteria for Chronic Pain.	Dr. Heston seconded the motion. The motion carried unanimously. Section 2: Dr. Unruh moved to approve as amended. Dr. Heston seconded the motion. The motion carried unanimously. Section 3: Dr. Unruh moved to approve as amended. Dr. Heston seconded the motion. The motion carried unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA CRITERIA Initial Approval: January 10, 2018 CRITERIA FOR PRIOR AUTHORIZATION Opioid Products Indicated for Pain Management (To supersede previous opioid PAs) PROVIDER GROUP Pharmacy MANUAL GUIDELINESThe following drugs require prior authorization: Long-Acting Opioids: **Includes both brand and generic versions of the listed products unless otherwise noted:** Buprenorphine (Butrans, Belbuca) Fentanyl transdermal (Duragesic) Hydrocodone extended-release (Zohydro ER, Hysingla ER, Vantrela ER) Hydromorphone extended-release (Exalgo) Methadone Morphine controlled-release/extended-release (Kadian ER, Avinza, MS Contin, Oramorph, Arymo ER) Morphine/Naltrexone (Embeda) Oxycodone extended-release (OxyContin) Oxycodone extended-release (Xtampza ER) Oxycodone/Naloxone (Targiniq ER) Oxycodone/Naltrexone (Troxyca ER) Oxymorphone extended-release (generic non-crush resistant) Oxymorphone extended-release (Opana ER-crush resistant) Tapentadol extended-release (Nucynta ER) Tramadol extended-release (Ultram ER, Ryzolt) Short-Acting Opioids: **Includes both brand and generic versions of the listed products unless otherwise noted:** (All salt forms, single and combination ingredient products, and all brand and generic formulations of the following): Codeine Dihydrocodeine Fentanyl Hydrocodone Hydromorphone Levorphanol Tartrate Meperidine Morphine Oxycodone Oxymorphone Pentazocine/Naloxone Tapentadol Tramadol 1. CRITERIA FOR OPIOID USE IN DIAGNOSIS OF CANCER, SICKLE CELL DISEASE, HOSPICE/PALLIATIVE CARE • Must meet one of the following: ○ Patient is being treated for pain related to active cancer diagnosis. ○ Patient is being treated for sickle cell disease. ○ Patient is receiving hospice or palliative care. ○ Fentanyl patches are only approved for patients with a diagnosis of cancer or for palliative care related pain. • Prescriber must have a KMAP ID. • Prescriber must be enrolled in the REMS program to prescribe for Trans mucosal Immediate Release Fentanyl (TIRF).	

TOPIC	DISCUSSION	DECISION AND/OR ACTION

APPROVED PA CRITERIA

Approval Duration: 12 months

2. CRITERIA FOR OPIOID USE IN NON CANCER, NON SICKLE CELL DISEASE, NON HOSPICE/PALLIATIVE CARE FOR ACUTE PAIN (patients with < 90 days of opioid medication in the past 120 days)

- No prior authorization is required for prescriptions equal to or for no more than a cumulative 14 day supply of opioids in the last 60 days within allowed limits.
    - Maximum of 7 day supply is allowed per fill.
    - Cumulative opioid dose must not exceed 90 MME per day.
    - Drug must not exceed maximum FDA approved dosage.
    - Drug requested must not be a long-acting opioid.
    - Prescriber must have a KMAP ID.
- Prior authorization is required to exceed 14 day supply of opioid medication in last 60 days (must meet all of the following):
    - Patient has attempted treatment with at least 2 non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants) in the last 90 days unless contraindicated.
    - Prescriber must have a KMAP ID.
    - Patient must not be taking more than one long-acting & one short-acting opioid analgesic, concurrently.
    - Cumulative opioid dose must not exceed 90 MME per day or maximum FDA approved dosage.
    - Drug requested is not a long-acting opioid.
    - Prescriber attests to the following:
        - Non-pharmacological treatment has been tried and/or is currently being used (e.g., exercise, cognitive behavior therapy, or interventional treatment)
        - Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program (PDMP) a.k.a K-TRACS.
        - Treatment duration and goals are defined with the patient and in the medical record.
        - Patient has been screened for substance abuse/opioid dependence.
        - If patient is concurrently on a CNS depressant (e.g., benzodiazepines), prescriber has reviewed and will address the increased risk of respiratory depression with the patient.
        - Patient has been screened for depression or other mental health illness.
            - If patient is positive for depression, patient is receiving either pharmacological or nonpharmacological treatment.

Renewal Criteria:

- Attempting to taper dose/frequency or
- Documentation in medical record the reason for not tapering the dose/frequency

Approval Duration: 1 month; Maximum of 2 renewals (3 months total)

3. CRITERIA FOR OPIOID USE IN NON CANCER, NON SICKLE CELL DISEASE, NON HOSPICE/PALLIATIVE CARE FOR CHRONIC PAIN (Patients with ≥90 days of opioid medication in the past 120 days)

- Prior authorization is required to exceed 90 day supply of opioid claims (must meet all of the following):
    - Patient has failed at least two (2) non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants) unless contraindicated.
    - Prescriber must have a KMAP ID.
    - Patient must not be taking more than one long-acting & one short-acting opioid analgesics, concurrently.
    - Prescriber attests to the following:
        - Non-pharmacological treatment has been tried and/or is currently being used. (e.g., exercise, cognitive behavior therapy, or interventional treatment).
        - Prescriber has reviewed controlled substance prescriptions in PDMP (K-TRACS).
    - Documentation of treatment duration and treatment goals to include:
        - Rationale for not tapering and discontinuing opioid.
        - Patient has a pain management/opioid agreement with the prescriber.
        - Patient has/will have random urine drug screens as part of their on-going therapy with opioids.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	APPROVED PA CRITERIA ▪ If patient is concurrently on a CNS depressant (e.g., benzodiazepines), prescriber has reviewed and will address the increased risk with respiratory depression with the patient. ▪ Patient has screened for depression or other mental health illness. • If patient is positive for depression, patient is receiving either pharmacological or nonpharmacological treatment. o Patient has been screened for substance abuse/opioid dependence. o If dose exceeds 90 MME per day, prescriber must attest to one of the following: ▪ Dose reduction has occurred since previous approval. ▪ Documentation that a dose taper has been attempted within the past 6 months and was not successful. o If request is for a long-acting opioid, must meet the following: ▪ Patient must have a documented history of failure, contraindication or intolerance to a trial of at least two preferred short-acting opioids. ▪ Patient must have received a short-acting opioid for greater than 30 days in the last 60 days. ▪ Trial and failure of at least two preferred long-acting opioids are required before the use of a non-preferred unless there is intolerance or contraindications. ▪ Methadone is only approved for diagnosis of terminal cancer pain. • If none of the above criteria are met, a one-time, one-month override is allowed for tapering. **Initial Approval Duration:** 3 months • Renewal Authorization Criteria for Chronic Pain o All narcotic analgesics are written by a single KMAP-enrolled prescriber or practice. o Documentation of treatment duration and treatment goals. o Prescriber provides rationale supporting inability to taper or discontinue opioid therapy. o Patient will not be maintained on more than one long-acting & one short-acting opioid analgesics, concurrently. o Patient has a pain management/opioid agreement with the prescriber (excluding patients in a long-term care facility). o Prescriber has reviewed controlled substance prescriptions in PDMP (KTRACS). o Patient has/will have random urine drug screens as part of their on-going therapy with opioids (excluding patients in a long-term care facility) o If the current dose exceeds 90 MME/day, one of the following criteria must be met: ▪ Dose reduction has occurred since previous approval; ▪ Documentation that a dose taper has been attempted within the past 6 months and was not successful. **Renewal Approval Duration:** 12 months NOTES: GENERAL CRITERIA FOR OPIOID MEDICATION USE: • Initial use max of 7-day fills (cumulative 14 day supply in 60 days) is allowed before PA will be required. • Ninety percent (90%) of medicine must be used prior to a refill unless a PA for early refill is approved. • Prescriber must attest to reviewing K-TRACS prior to writing every new opioid prescription. • Prescriber should calculate total MME per day for concurrent opioid medications. • Initial use of immediate-release opioids is required before use of ER/LA opioids. • Provider attests to limiting and avoiding where possible the concurrent use of CNS depressants, especially benzodiazepines, when prescribing opioids. • Before starting & periodically, an evaluation of risk factors for opioid related harms should be done. • Non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants) and non-pharmacological treatments should be tried first unless contraindicated. • Prescriber has screened patient for depression and substance use disorder. • New dosage forms or strengths to agents listed can be added as they become available. • Drug must not exceed maximum FDA approved dosage. • Physician must consider use of opioids and Neonatal Opioid Withdrawal Syndrome if patient is pregnant.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
D. Miscellaneous Items 1. Fee-for-Service Retrospective Drug Utilization Review Topic Selections i. Topic Presentations	**Background:** The DUR Board will select topics for the two (2) RDUR intervention topics between February and June 2018. **Board Discussion:** None.	Tabled to April, 2018 Meeting
IV. Open Public Comment:	None.	
V. Adjourn:		Dr. Mittal adjourned the January 10, 2018 DUR Meeting at 2:00pm.

The next DUR Board meeting is scheduled for April 11 2018.

Public Comment: is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

ACRONYMS: CDC = CENTER FOR DISEASE CONTROL, CMS = CENTERS FOR MEDICAID AND MEDICARE SERVICES, KDHE = KANSAS DEPT. OF HEALTH AND ENVIRONMENT, KDADS = KANSAS DEPARTMENT FOR AGING AND DISABILITY SERVICES, MCO = MANAGED CARE ORGANIZATION